

Charter

Berkeley Laboratory Institutional Animal Care and Use Committee (IACUC)

Regulatory Basis:

Experimental animal use at the Laboratory is reviewed and monitored by a legally mandated Institutional Animal Care and Use Committee as stipulated in “Public Health Service (PHS) Policy on Humane Care and Use of Laboratory Animals”. This committee, entitled the **Animal Welfare and Research Committee (AWRC)**, was established at LBNL in 1985 when Public Health Service Act (Public Law 99-158) set the standards for establishing oversight, setting responsibilities and functions for implementation of institutional review committees. Since its inception the committee has operated in full compliance with the enabling act and its updates and PHS (now Department of Health and Human Services) guidelines.

This charter is applicable to all research, research training, experimentation, and biological testing and related activities involving live, vertebrate animals conducted at this institution regardless of source or fact of funding, or at another institution as a consequence of subgranting or subcontracting of an activity supported by this institution.

Membership/Composition:

Members are appointed by the Institutional Official or his designee(s) to three-year terms with the option of renewal for subsequent three-year periods. The Chairman and a Vice-Chairman also serve at the pleasure of the Laboratory Director for a term of three years. Membership planning will be discussed at the February meeting each year. Upcoming vacancies, term expirations, reappointments, and other membership needs will be assessed.

Committee membership includes two representatives and an alternate from the research community, at least one veterinarian with a specialty in laboratory animal medicine (preferably documented by board certification in laboratory animal medicine), and up to two members of the community. At least one of the community members should be able to represent bioethical concerns. Appointments are staggered so that a portion of the committee changes each year and experienced membership is assured.

In addition to these appointed members, the AWRC Compliance Specialist of the Human and Animal Regulatory Committee office shall serve as a non-voting member *ex officio*. The Animal Colony Manager serves as a non-voting, *ex officio* member. Either or both the Compliance Specialist and the Animal Colony Manager may, at the discretion of the AWRC and the Institutional Official, be made a voting member.

AWRC Responsibilities:

1. Review at least once every six months the Laboratory’s program for humane care and use of animals using the “Guide” as a basis for evaluation;

2. Inspect at least once every six months all of the Laboratory's animal facilities using the "Guide" as a basis for evaluation.
3. Prepare and submit reports of six-month evaluations of the animal use and care program to the Institutional Official or his/her designee(s).
4. Review concerns involving the care and use of animals and report as needed to the Institutional Official or his/her designee(s).
5. Make recommendations to the Institutional Official or his/her designee(s) regarding any aspect of the Laboratory's animal program, facilities, or personnel training.
6. Review and approve, require modifications in or withhold approval of activities related to the care and use of animals in support of research at the Laboratory.
7. Review and approve, require modifications in, or withhold approval of proposed significant changes regarding the use of animals in support of ongoing research. Significant changes include, but are not limited to, changes in the hypothetical basis for the research or the underlying experimental approach and a greater than 10 percent deviation in the projected number of animals used in a year.
8. Suspend animal use for an activity not in accordance with the approved protocol, LBNL's Assurance, or the "Guide".

Review Processes:

The Animal Welfare and Research Committee conducts different levels of review for different types of protocols and the renewal and modification of those protocols. Tier one reviews are the simplest and are for things like adding personnel and shipping animals to a PHS assured facility. Tier two reviews are more complex and involve things like modifying an approved protocol to add a procedure, add animals, or create a new protocol to ship animals to a non-PHS assured facility. Tier three reviews are the most complex, and involve the initial review of on-site animal use protocols and the triennial renewal and major modification of those protocols, and collaborative protocols with other sites where animals will be used in experimental research. Each protocol and modification is reviewed for animal use and must address the need for using animals, the appropriateness of the animal species selected as a model and the numbers to be used, and the relationship of the experimental protocol to the research proposed or being conducted. Researchers are required to demonstrate that alternatives to using animals have been thoroughly explored. The different areas covered by the different levels of review are detailed in sections 1-3 below, but all reviews consider the following criteria, where relevant. In all cases, individual committee member comments will be kept anonymous.

- a. Procedures with animals avoid or minimize discomfort, distress, and pain, consistent with sound research design.
- b. Procedures that may cause more than momentary or slight pain or distress to animals is performed with appropriate sedation, analgesia, or anesthesia, unless these mitigating steps are justified in writing as detrimental to achieving research goals.

- c. Animals otherwise experiencing severe pain or chronic pain or distress that cannot be relieved will be painlessly euthanized at the end of the procedure or, if appropriate, during the procedure.
- d. Living conditions of animals on a research project are appropriate for their species and contribute to their health and comfort. The housing, feeding, and non-medical care of the animals will be directed by a veterinarian or other scientist trained and experienced in the proper care, handling, and use to the species being maintained or studied.
- e. Medical care for animals is available and provided as necessary by a qualified veterinarian.
- f. Personnel conducting procedures on the species being maintained or studied will be appropriately qualified and trained in those procedures.
- g. A plan for routine monitoring of animal condition by the researcher or his/her staff is in place. This plan must be adequate to insure that humane standards are maintained and research goals are met.
- h. Methods of euthanasia used will be consistent with the recommendations of the American veterinary Medical Association (AVMA) Panel on Euthanasia unless a deviation is justified in writing as having an adverse impact on research.
- i. Methods used for animal identification must not lead to animal mutilation. Tattoos, ear punch, wireless implanted transponders, and hair dyes are acceptable. Methods resulting in mutilation, such as toe clipping, are not acceptable.

Reviews can either be handled one of three ways. Tier One, or administrative, reviews are for shipping animals or antibody production by a PHS assured commercial lab, or for a simple modification of a protocol for such things as adding new staff. These reviews are completed by the Chair and at least one other committee member. Tier Two, or designated member, reviews are for more substantial protocol modifications or for certain types of collaborative protocols (see attached list). These reviews will be designated as being appropriate for DMR by consensus between the Chair, the AV and HARC staff. Materials will be circulated to all AWRC members and objections to handling the review via the DMR process will be solicited, with a deadline of typically 3 business days given for the registering of such objections. If no objections to DMR have been made by any committee member the Chair will designate at least two members of the AWRC to conduct the review. Tier Three, or full committee reviews, must be performed on all LBNL protocols where animals will be used on site, on most joint research collaboration protocols and any protocol modification that cannot be handled via the designated member review process. Tier three reviews must go through veterinary pre-review, and be considered at convened meetings of the AWRC. In all cases, individual committee member responses and comments will be kept anonymous.

For more details on the categories suitable for Tier one, two, and three reviews, and on the process, see the “LBNL Animal Use Protocol Review Tiers” document.

Voting: the following categories are used in all types of review:

Approved - Fully approved with no conditions.

Clarification Required - Approved with conditions so minor and/or clearly spelled out that they can be reviewed by the staff, chair, or specified Committee member.

Deferred - Deferred due to conditions serious enough to warrant the investigator's response being reviewed by the entire Committee.

Tabled - No vote taken, because the protocol was deficient preventing a competent review. Such protocols are always returned to the Committee for full review after revisions are made.

1. The AWRC may invite consultants to assist in the review of complex issues. Consultants provide advice and recommendations for action but may not approve or withhold approval of an activity or vote.
2. The AWRC notifies investigators and the institution in via email of its decision to approve or withhold approval of those activities related to the care and use of animals, or modifications required to secure approval. If the AWRC decides to withhold approval of an activity, written notification shall include a statement of the reasons for its decision and give the investigator an opportunity to respond in person and/or in writing.
3. The AWRC conducts continuing review of activities in approved protocols annually, and comprehensive review of ongoing protocols not less than every three years.
4. The AWRC has the responsibility to suspend any activity that it previously approved if it determines that the activity is not being conducted in accordance with the approved protocol, the provisions of the Animal Welfare Act, the "Guide", or LBNL's Assurance. The AWRC may take such action only after a review of the matter at a convened meeting of a quorum of the Committee and with the suspension vote of a majority of the quorum present.
5. If the AWRC suspends an activity involving animals, the Laboratory Director or his designee(s) in consultation with the AWRC shall review the reasons for suspension, take appropriate corrective action, and report the action with a full explanation to the Office for the Protection of Research Resources of DHHS.
6. Applications and proposals that have been approved by the AWRC may be subject to further review and approval by the Laboratory Director or his designees. However, those officials may not approve an activity involving the care and use of animals not sanctioned by the AWRC.

References:

Guide for the Care and Use of Laboratory Animals, (the *Guide*), Institute of Laboratory Animal Resources.

AVMA Guidelines for the Euthanasia of Animals: 2013 (2013 or later editions), American Veterinary Medical Association

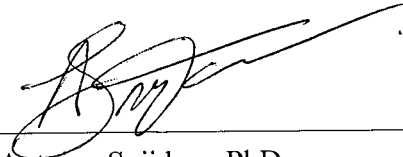
Excerpt from Minutes of 10 October 1985:

“...name Animal Welfare and Research Committee accurately reflects the committee’s role – in addition to the continuing concern for animal care and handling, the AWRC will become more actively involved with research protocols to insure appropriate use of animals in LBL projects. It is the goal of AWRC to work positively with LBL investigators to make sure that the animal use in all LBL research programs is necessary (that there is not another way to obtain the same information without the use of animals), is efficient (that the appropriate species and number of animals will be used), and is conducted humanely (that the care and handling of animals conforms to standards of current PHS guidelines).

The Principles of Humane Experimental Techniques, W.M.S. Russell and R.L. Burch.



Horst Simon, PhD
LBNL Institutional Official



Antoine Snijders, PhD
Chair, Animal Welfare and Research Cmte.